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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,464	02/11/2002	James Tiedje	MSU-06787	4392

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COZEN O'CONNOR, P.C.
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EXAMINER

JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/073,464	Applicant(s) TIEDJE ET AL.	
	Examiner Diana B. Johannsen	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☒ Claim(s) 1-15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>0703</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The paper and computer readable forms of the Sequence Listing filed July 23, 2002 have been entered. The Amendment and Response filed July 2, 2003 has also been entered. Claims 1 and 9 have been amended, and claims 16-21 have been canceled. Claims 1-15 are now pending and under consideration.

Election/Restriction

2. Applicant's election without traverse of Group I, claims 1-15 in the Amendment and Response of July 2, 2003 is acknowledged. It is again noted that non-elected claims 16-21 have been canceled.

Information Disclosure Statement

3. The information disclosure statement filed July 2, 2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Specifically, Applicant has not provided a copy of reference 33 (Sokal and Sneath). Accordingly, this reference has not been considered.

It is also noted that several citations provided on Applicant's Form PTO-1449 were incomplete. Several citations were completed by the examiner, and it is requested that Applicant review and acknowledge review of the corrections made by the examiner. It is further noted that references 44-55 have not been considered. Complete citations for the documents provided by Applicant have not been listed. Further, it is not clear whether Applicant's intent was to cite the provided documents pertaining to the recited strains (or whether Applicant is attempting to cite bacterial strains themselves).

Specification

4. The use of the trademarks QIAQUICK, PICOGREEN, GENEPIX, and GENBANK has been noted in this application. The trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

5. The present title of the invention pertains to a product, and is not descriptive of the claimed methods. A new title is required that is clearly indicative of the invention to which the claims are directed.

Oath/Declaration

6. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

- a) The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 601.01(a). Specifically, the oath/declaration recites the serial number and filing date of a provisional application of which the instant application claims benefit, rather than the serial number and filing date of the present application;
- b) The oath/declaration also includes a priority claim under 35 USC 120 (rather than 35 USC 119(e)) to that same provisional application.

Claim Objections

7. Claims 1-15 are objected to because of the following informalities: independent claims 1 and 9 refer to “a test bacteria” rather than either “a test bacterium” or “test bacteria.” Appropriate correction is required. It is noted that several dependent claims refer back to “test bacteria” (plural).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-8 are indefinite over the recitation of the phrase “labeled reference DNA from at least four strains of bacteria represented on said solid support” in claim 1. It is unclear as to whether this language requires that “labeled reference DNA from at least four strains of bacteria” be present on “said solid support,” or whether the claims require a solid support comprising “amplified genomic sequences” from at least four strains of bacteria, as well as “labeled reference DNA” from at least four of these strains in some other form (e.g., in solution). Clarification is required.

Claims 1-8 are indefinite over the recitation of the limitation “said arrayed sequences” in claim 1. While the claim previously refers to “amplified genomic sequences” and to a “plurality of arrayed elements,” the claim does not previously recite the term “arrayed sequences.”

Claims 1-8 are indefinite over the recitation of the phrase “calculating the hybridization signal intensity ratio at each array element to determine the identity of said test bacteria” in claim 1. It is noted that the claim as written encompasses, e.g., the use of identically labeled target and reference DNA, target and reference DNAs hybridized to either the same or different solid supports, etc. The specification describes the calculation of “Hybridization signal ratios (*R*) between test and reference DNA” (page 34), and provides a definition at page 17 for the term “signal to noise ratio” which states that such a ratio is “computed by taking the ratio of levels of the desired signal to the level of noise present within the signal.” However, the specification does not provide any type of limiting definition for the term “hybridization signal intensity ratio,” and the claims do not indicate what signals are compared to obtain such a ratio. Accordingly, it is unclear as to what type of calculation or calculations is/are actually encompassed by this recitation in the claims, as well as to how such calculation(s) allow one “to determine the identity of said test bacteria.”

Claim 8 is indefinite over the recitation of the limitation “said test and reference bacteria.” While claim 1 refers to “test bacteria,” there is insufficient antecedent basis for “reference bacteria” in the claims.

Claims 9-15 are indefinite over the recitation of the phrase “labeled reference DNA from at least four strains of bacteria represented on said at least one microchip” in claim 9. It is unclear as to whether this language requires that “labeled reference DNA from at least four strains of bacteria” be present on “said at least one microchip,” or whether the claims require that said “at least one microchip” comprise “amplified

genomic sequences” from at least four strains of bacteria, as well as “labeled reference DNA” from at least four of these strains in some other form (e.g., in solution).

Clarification is required.

Claims 9-15 are indefinite over the recitation of the limitation “said arrayed sequences” in claim 9. While the claim previously refers to “amplified genomic sequences” and to a “plurality of arrayed elements,” the claim does not previously recite the term “arrayed sequences.”

Claims 9-15 are indefinite over the recitation of the phrase “calculating the hybridization signal intensity ratio at each array element to determine the identity of said test bacteria” in claim 9. It is noted that the claim as written encompasses, e.g., the use of identically labeled target and reference DNA, target and reference DNAs hybridized to either the same or different microchips, etc. The specification describes the calculation of “Hybridization signal ratios (R) between test and reference DNA” (page 34), and provides a definition at page 17 for the term “signal to noise ratio” which states that such a ratio is “computed by taking the ratio of levels of the desired signal to the level of noise present within the signal.” However, the specification does not provide any type of limiting definition for the term “hybridization signal intensity ratio,” and the claims do not indicate what signals are compared to obtain such a ratio. Accordingly, it is unclear as to what type of calculation or calculations is/are actually encompassed by this recitation in the claims, as well as to how such calculation(s) allow one “to determine the identity of said test bacteria.”

Claim 13 is indefinite over the recitation of the limitation "said test and reference bacteria." While claim 9 refers to "test bacteria," there is insufficient antecedent basis for "reference bacteria" in the claims.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Straus (US 2002/0086289 A1 [published 7/2002; filed 6/1999]), as evidenced by DeRisi et al (Science 278:680-686 [10/1997]).

Straus discloses a method for identifying bacteria in which labeled target DNA from a test sample including bacteria is hybridized to a "detection ensemble" of detection sequences from 5 or more distinct genomes arrayed on a solid support (see entire reference, particular pages 3-4 and the definition of "minimum genomic derivation" at pages 7-8). Straus teaches that in embodiments of his invention, the detection sequences arrayed on a solid support are amplified genomic DNAs (see, e.g., page 17, right column). Straus further discloses both the combination of positive and negative control probes with test sample molecules prior to hybridization (see, e.g., page 19), and preparation of a database of fingerprints with which test sample patterns

may be compared (see, e.g., page 28). Regarding the step of "calculating hybridization signal intensity ratio at each array element," it is noted that Straus states that "Microarrays are scanned with a laser fluorescent scanner, and signals are processed and recorded as is described in published reports," referring to the DeRisi et al reference (page 25). The DeRisi et al reference discloses that processing and recording of signals comprises calculation of a hybridization signal intensity ratio (see entire reference, particularly footnote 49). Accordingly, it is an inherent property of the method disclosed by Straus that it includes such a step, and therefore Straus anticipates the instant claims.

Regarding claims 5 and 9-15, it is further noted that the solid supports disclosed by Straus include microchips (see, e.g., page 10). Regarding claims 2-4 and 10-12, it is noted that the samples disclosed by Straus include samples from a test subject, samples comprising pathogens, and environmental samples (see pages 4, 10, and 12). Regarding claim 6, the processing disclosed by DeRisi et al comprises statistical analysis (see footnote 49 of DeRisi et al).

Conclusion

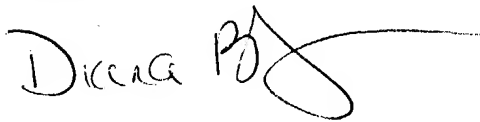
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

A handwritten signature in black ink, appearing to read "Diana B. Johannsen", followed by a long, sweeping horizontal line.

Diana B. Johannsen
November 14, 2003